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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA et al., *ex rel.* JESSICA PENELOW AND CHRISTINE BRANCACCIO, *Plaintiffs*, v. JOHNSON & JOHNSON, JANSSEN PRODUCTS, LP, *Defendants*.	Hon. Peter G. Sheridan Civil Action No. 12-7758 (PGS) **STATEMENT OF INTEREST RE: DEFENDANT JANSSEN'S MOTION TO DISMISS**

The False Claims Act ("FCA"), 31 U.S.C. § 3729 *et seq.*, is the federal government's primary tool to combat fraud and recover losses due to fraud in federal programs. Accordingly, the United States has a substantial interest in the proper interpretation of the FCA. The United States also administers the Medicare and Medicaid programs, and therefore has a substantial interest in the proper interpretation of the statutes, regulations, and guidance that govern those programs. The United States submits this statement of interest to address arguments made by Defendant Janssen Products, LP ("Janssen") in its Motion to Dismiss that drugs prescribed for indications approved by the Food and Drug Administration ("FDA") are per se "reasonable and necessary" for purposes of Medicare and Medicaid reimbursement and that false statements that induce a physician to prescribe a particular drug can never be actionable under the FCA if the

drug is prescribed for an FDA-approved indication. The government takes no position on whether the allegations in the relators' complaint are sufficient to survive dismissal under Rule 9(b) of the Federal Rules of Civil Procedure.

BACKGROUND

A. The False Claims Act

The FCA is "the Government's primary litigative tool" for combatting fraud, and was intended "to reach all fraudulent attempts to cause the Government to pay out sums of money." S. Rep. No. 99-345, at 2, 9 (1986). Congress therefore drafted the statute "expansively . . . 'to reach all types of fraud, without qualification, that might result in financial loss to the Government.'" *Cook Cty. v. United States ex rel. Chandler*, 538 U.S. 119, 129 (2003).

An FCA violation occurs when a person "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval." 31 U.S.C. § 3729(a)(1)(A). A violation also occurs when a person "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." *Id.* § 3729(a)(1)(B).[1] The FCA authorizes suits to collect statutory damages and penalties either by the Attorney General or by a private person (known as a *qui tam* relator) in the name of the United States. 31 U.S.C. § 3730(a), (b)(1); *see also Vermont Agency of Nat. Res. v. United States ex rel. Stevens*, 529 U.S. 765, 769-78 (2000). If a relator files a *qui tam* action, the government may intervene and take over the

[1] The current version of these provisions took effect on May 20, 2009, after passage of the Fraud Enforcement and Recovery Act of 2009, Pub. L. No. 111-21, § 4, 123 Stat. 1617, 1621-25. The prior version had some differences in wording. *See* 31 U.S.C. § 3729(a)(1) (2006) (creating liability for any person who "knowingly presents, or causes to be presented" to a federal employee or official "a false or fraudulent claim for payment or approval"); *id.* § 3729(a)(2) (creating liability for any person who "knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government").

case. 31 U.S.C. § 3730(b)(2). If the government declines to intervene, the relator conducts the litigation. *Id.* § 3730(c)(3). Monetary proceeds from a *qui tam* suit are divided between the government and the relator. *Id.* § 3730(d).

B. Prescription Drug Approval and Coverage

Under the Federal Food, Drug, and Cosmetic Act, the FDA must approve a drug before a manufacturer can market the drug in the United States. FDA will approve a new drug application only after determining, among other things, that the new drug is safe and effective for its intended use. *See generally* 21 U.S.C. § 355.

Medicare Part D and Medicaid both provide prescription drug coverage to beneficiaries. Both programs are overseen by the Centers for Medicare and Medicaid Services ("CMS") within the Department of Health and Human Services. Part D plans are designed and administered in the first instance by third-party plan sponsors that contract with CMS. Medicaid plans are administered by the states. Although different plans may have different requirements for reimbursement, the statutes, regulations, and guidance that govern the Medicare Part D and Medicaid programs impose certain requirements on all plans.

Among other requirements, the Medicare statute expressly prohibits reimbursement for items and services that "are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." 42 U.S.C. § 1395y(a)(1)(A). Physicians and other qualified medical providers provide the first line of defense in enforcing the "reasonable and necessary" requirement. A doctor's prescription is generally required for drug coverage under Medicare Part D or Medicaid. 42 U.S.C. §§ 1395w-102(e)(1)(A), 1396r-8(k)(2)(A), (k)(4); 42 C.F.R. § 423.104(h); Medicare Prescription Drug Benefit Manual, Chapter 6, Transmittal 10.1 ("[A] Part D drug means a drug that may be

dispensed only upon a prescription. . . .") and Transmittal 20.1 ("[A] Part D sponsor may exclude from qualified prescription drug coverage any Part D drug. . . . [w]hich is not prescribed in accordance with the Part D sponsor."). FDA approval is a further precondition for coverage and payment, with certain narrow exceptions. *See* 42 U.S.C. § 1396r-8(k)(2)(A) (defining "covered outpatient drug" for Medicaid purposes); *id*. § 1395w-102(e)(1) (relying in part on Medicaid definition for Medicare Part D). Both Part D and Medicaid plans may deny coverage on necessity grounds even if a drug is prescribed for an FDA-approved indication. *See* 42 U.S.C. § 1395w-102(e)(3)(A) (stating that Part D plan "may" exclude from coverage items that would not be "reasonable and necessary" under the Parts A and B definition); 42 C.F.R. § 440.230 (stating that Medicaid plans "may" limit service based on "medical necessity"); *see also* 42 U.S.C. § 1396r-8(d)(4)(C); 42 C.F.R. § 456.705. A drug must also be used for a "medically accepted" indication – one that is approved by FDA or supported by certain third-party compendia or other authorities. *See* 42 U.S.C. § 1395x(t)(2) (discussing drugs used in an anticancer chemotherapeutic regimen); 42 C.F.R. § 414.930 (relevant compendia for drugs used in an anticancer chemotherapeutic regimen).

C. The Present Litigation

Janssen owns Prezista and Intelence, two prescription drugs approved by FDA for HIV treatment. Relators generally allege that Janssen caused false claims to be submitted to federal healthcare programs through "off-label marketing, misbranding, and kickback schemes" related to Prezista and Intelence. The United States declined to intervene, and relators are proceeding with the litigation.

ARGUMENT

In its motion to dismiss, Janssen broadly argues that an FDA-approved drug prescribed for its on-label use is always "reasonable and necessary" and covered under Medicare Part D and Medicaid. Based on this argument, Janssen concludes that false statements that induce a physician to prescribe a particular drug treatment can never be actionable if the drug is approved and prescribed for its on-label indication because the drug is per se "reasonable and necessary." These arguments raise significant questions regarding the criteria for Medicare and Medicaid reimbursement and the circumstances under which false or fraudulent statements to physicians can lead to FCA liability.

A. A DRUG IS NOT PER SE "REASONABLE AND NECESSARY" SIMPLY BECAUSE IT WAS PRESCRIBED FOR AN FDA-APPROVED INDICATION

In its motion to dismiss, Janssen contends that because Prezista and Intelence were approved by FDA for the treatment of HIV, any prescription of those two drugs to treat HIV would be "reasonable and necessary" as a matter of law. However, a drug treatment is not per se "reasonable and necessary" simply because it was prescribed for an FDA-approved indication. As discussed above, CMS has identified other factors relevant to the "reasonable and necessary" determination, including whether a physician prescribed the drug. Indeed, CMS may determine that a drug treatment is not "reasonable and necessary" even if it is prescribed for an FDA-approved use. *Cf. Almy v. Sebelius*, 679 F.3d 297, 308 (4th Cir. 2012) ("While FDA approval [for a medical device] may . . . inform the Secretary's decision as to whether a device is 'reasonable and necessary,' it cannot tie the Secretary's hands."). To reach a contrary conclusion would unduly limit CMS in executing its statutory authority to review whether an item or service is reasonable and necessary. Accordingly, this Court should clarify that the "reasonable and

necessary" requirement is not limited to whether a drug treatment is prescribed for a "medically accepted" use.

B. FRAUD DIRECTED AT PHYSICIANS MAY ESTABLISH FCA LIABILITY IF GOVERNMENT REIMBURSEMENT WAS A REASONABLY FORESEEABLE RESULT

Janssen argues that a defendant can never be subject to FCA liability for making false statements that induce a physician to prescribe a drug treatment paid for by the United States. Janssen suggests that physicians' actions are irrelevant because the "reasonable and necessary" requirement is limited to whether a drug treatment is prescribed for a "medically accepted" use. However, Janssen ignores the essential role that physicians play in the reimbursement process. *Goodman v. Sullivan*, 891 F.2d 449, 450 (2d Cir. 1989) ("Congress intend[ed] the physician to be a key figure in determining what services are needed and consequently reimbursable."). A physician's prescription is generally a prerequisite to reimbursement for drug treatments. Fraud that corrupts this process by inducing physicians to prescribe a drug when they would not do so otherwise is actionable under the FCA.

Under Supreme Court and Third Circuit precedent, a defendant can be liable for fraudulent efforts to obtain government money even if the fraud was directed in the first instance at a third party integral to the payment process, rather than at the United States. Fraud directed at physicians may therefore establish FCA liability if government reimbursement was a reasonably foreseeable result. In such a case, the fraud would be "an important, even an essential factor in subjecting the government to an enforceable demand for money." *United States v. Veneziale*, 268 F.2d 504, 505 (3d Cir. 1959). Liability may therefore attach because the perpetrator "caus[ed] the government to pay claims which were grounded in fraud," regardless of whether "that person had direct contractual relations with the government." *Marcus v. Hess*, 317 U.S. 537, 544 (1943).

The Supreme Court's decision in *Hess* is instructive. In *Hess*, the defendants submitted collusive bids to local governments for various projects. The bidders were aware that these projects were partly funded by the federal government, but they lacked any direct contractual relationship with the United States. *Hess*, 317 U.S. at 542-43. The Supreme Court nonetheless concluded that the bidders were subject to FCA liability because their fraudulent conduct "caused the [United States] to pay claims of the local sponsors in order that they might in turn pay [the defendants] under contracts found to have been executed as the result of the fraudulent bidding." *Id.* at 543. "The initial fraudulent action and every step thereafter taken, pressed ever to the ultimate goal – payment of government money to persons who had caused it to be defrauded." *Id.* at 543-44. As a result, the "fraud did not spend itself with the execution of the contract," but rather "taint[ed]" the later claims that caused the United States to reimburse the local governments. *Id.* at 543.

A reimbursement claim may likewise be "fraudulent" if a defendant fraudulently induces a physician to prescribe a drug treatment paid for by Medicare or Medicaid. In such a case, the fraud committed on the physician would not "spend itself" with the physician's decision to prescribe a drug (and, if applicable, submit a reimbursement claim and certify the treatment's medical necessity), but would "taint" the resulting request for reimbursement.

The United States does not contend that a claim is necessarily false or fraudulent simply because an antecedent fraud was a "but for" cause of the claim's submission. But liability may attach where the connection between the fraud and the claim is sufficiently close. That would be the case if, for example, a relator could demonstrate that a defendant's fraud was intended to induce physicians to prescribe a drug and it was reasonably foreseeable that the federal government would pay for the treatment. *Cf. In re Neurontin Mktg. & Sales Practices Litig.*, 712

F.3d 21, 39 (1st Cir. 2013) (finding for purposes of RICO claim that fraudulent marketing to doctors was proximate cause of economic loss to private insurer that had to pay for increased prescriptions).

A defendant in such a case cannot escape liability because it directed its fraud in the first instance at a third party integral to the reimbursement process, rather than at the United States. In *Hess*, the Supreme Court held that the FCA applies to fraudulent conduct that causes a third party to submit claims to the United States for amounts higher than would have been submitted otherwise, even absent any false statement to the United States itself. 317 U.S. at 542-44. The Third Circuit in *United States v. Lagerbusch*, 361 F.2d 449, 449 (3d Cir. 1966), likewise held that an employee was liable under the FCA for making false representations to obtain money from his employer, a government contractor reimbursed by the United States. *Lagerbusch* rejected the argument that the FCA did not apply because the false statements were not made to the United States. Citing *Hess*, the Court held that "[w]e have no doubt that the False Claims Act covers such an indirect mulcting of the government." *Lagerbusch*, 361 F.2d at 449. The Senate Judiciary Committee later endorsed *Lagerbusch* in the legislative history of the 1986 amendments to the False Claims Act, explaining that "a false claim is actionable although the claims or false statements were made to a party other than the Government, if the payment thereon would ultimately result in a loss to the United States." S. Rep. No. 99-345, at 10.

The United States takes no position on whether the relator has adequately alleged a False Claims Act violation under this theory. But the Court should not adopt Janssen's argument that suits under this theory can never be viable.

CONCLUSION

For the foregoing reasons, the Court's decision in this case should reflect that (1) a drug treatment is not per se "reasonable and necessary" simply because it was prescribed for an FDA-approved indication; and (2) FCA liability may attach in some cases if a defendant fraudulently induces a physician to prescribe a drug treatment paid for by the United States.

Dated: February 10, 2017
Newark, New Jersey

Respectfully submitted,

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CERTIFICATE OF SERVICE

Re: *United States, et al., ex rel. Penelow and Brancaccio v. Johnson & Johnson, et al.*

Civil Action No. 12-7758

I, Assistant U.S. Attorney Charles Graybow, hereby certify that on February 10, 2017, I caused a copy of the Statement of Interest of the United States, in the above-referenced matter, to be served on the following, pursuant to the United States District Court, District of New Jersey, Electronic Case Filing Policies and Procedures § 14(b)(1) (amended September 1, 2008):

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I certify under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

Dated: February 10, 2017
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